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EXAMINER	
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ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,299	WOOD ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,14-26 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,14-26 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 7/30/07 and 10/15/07 have been entered.

Response to Amendments

Applicant's amendments filed 10/15/07 to claims 14 and 29-31 have been entered. No claims have been cancelled in this reply. Claims 32 and 33 have been added. Claims 6, 14-26, and 29-33 remain pending in the current application, all of which are being considered on their merits. Prior art references not included with this Office action can be found in a prior action.

Claim Objections

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 33 appears to be identical in scope to claim 22. Applicant is required to cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, or point out how the scope of claim 33 differs from that of claim 22.

Claim Rejections - 35 USC § 112

Any rejections under 35 U.S.C. § 112 not addressed below are withdrawn in light of the claim amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 14-26, and 29-33 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (c) of claim 29 refers to "xenogenic serum," but no point of reference is provided for the relative term "xenogenic." Clarification is required. Applicant alleges that those skilled in the art would understand "xenogenic" to mean "avoidance of ingredients such as bovine serum albumin" (Reply, page 9, paragraph 3). These arguments have been fully considered, but they are not persuasive. The claim recites two different entities that could reasonably be the basis for the relative term "xenogenic," i.e. the cells and the patient. Applicant has simply not clarified this issue in the claims. The assertion that the person of ordinary skill in the art would understand "xenogenic" to mean "free of BSA" is not supported by the claims, which place no limit on the source of the cells or the species of the patient; indeed, the patient may be a cow. Claims 30-33 also recite this limitation and are indefinite for the same reasons.

Because claims 6 and 14-26 depend from indefinite claim 29 and do not clarify these points of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 6 requires that the composition of claim 5 be prepared from "autologous cells," but no point of reference is provided for the relative term "autologous." Clarification is required. Applicant alleges that the person of ordinary skill in the art would understand that "autologous" refers to the patient in claim 29, but as discussed above, this term could also reasonably apply to the cells.

Claim 14 requires that step (a) of claim 29 "comprises the **use** of an enzyme solution to chemically dissociate the cells from cellular stratum," which is confusing. The claim term "use" does not set forth any particular active method step. If the claim means to indicate that step (a) comprises contacting the tissue sample with an enzyme solution, e.g., it should be amended as such.

New claims 32 and 33 are drawn to "a first intermediate cell suspension" and "a second intermediate cell suspension," which is confusing for several reasons. These claims are both independent claims. The term "first" in claim 32 is confusing, since there is no corresponding "second" element in claim 32. Similarly, the term "second" in claim 33 is confusing, since there is no corresponding "first" element in claim 33. Finally, claims 32 and 33 refer to "intermediate" cell suspensions, but there is no point of reference for this relative term. These claims should be amended such that they clearly stand alone and claim particular inventions that are distinct from that of claims 29-31.

Claim 32 is drawn to a "suspension" according to its preamble, but the components do not necessarily describe a suspension. Component (a) includes a sample "under conditions suitable to" dissociate the sample, but there is not necessarily any dissociation. Similarly, step (b) includes a conditional harvesting element, and step

(c) includes a conditional filtering element. All that is necessarily recited in claim 32 is a skin tissue sample in a heated enzyme solution. Clarification is required. The claim should be amended such that it clearly and distinctly describes a particular composition.

Element (b) of claims 32 and 33 refer to a nutrient solution "capable of maintaining the viability of the cells," which does not require that viability actually be maintained. Clarification is required.

Claims 32 and 33 recite the limitations "autologous" and "xenogenic," which are indefinite for reasons set forth above and in previous Office actions. Clarification is required.

It is not clear whether the composition of claim 33 includes cell conglomerates, since the filtering element is optional. Clarification is required.

Claim Rejections - 35 USC § 102

The rejection of claim 22 over Dennis et al. is withdrawn in light of the amendment to this claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 14-24, 29, and 33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Yannas et al. (1983, U.S. Patent 4,418,691). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline.

Yannas et al. teach a composition comprising cells dissociated from skin (column 4, lines 58-60), said cells suspended in physiological saline (column 5, lines 3-6), and said cells separated from each other (column 4, line 66, through column 5, line 1).

Claims 29 and 32 are product-by-process claims; claims 6 and 14-24 depend from claim 29. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or

where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in the cited claims produce a composition that is materially and patentably distinct from the skin cell suspension of Yannas et al.

Applicant alleges that the method of Yannas et al. includes growing the cells on "a template for subsequence [sic] application to a defect," an element not included in

the instant claims (Reply, page 10, paragraph 4). Applicant alleges that the instant method does not require "other aspects" of Yannas et al.'s method. These arguments have been fully considered, but they are not persuasive.

Yannas teaches a suspension of cells obtained by dissociating a skin biopsy with enzymes (column 5, lines 50-51); this suspension is subsequently centrifuged into a collagen/glycosaminoglycan lattice (see, e.g., column 5, line 65). Yannas explicitly teaches that the suspension is made first and then introduced to the collagen/GAG lattice (column 5, lines 61-63). Therefore, Yannas teaches a suspension *per se* in addition to a composition comprising cells and a collagen/GAG lattice. The fact that the suspension is not the final product of the method of Yannas does not mean that the teachings of Yannas do not anticipate the suspension.

Applicant's allegation that the claims do not require "other aspects" of the Yannas teaching do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Claims 6, 14-21, and 23-31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (1990, EP 0 350 887; reference C2 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the nutrient media is a

saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Suzuki et al. teach a composition comprising cells dissociated from heart tissue (Reference Example 1; page 4, lines 50-54), said composition lacking aggregates removed by a No. 100 (150μm) filter (page 4, line 55); and a physiological saline, specifically HEPES buffer (page 4, lines 52-56). The 150μm filter of Suzuki et al. is a size of "about 200μm," since the scope of "about" is not limited by the specification.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in the cited claims produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Suzuki et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that Suzuki does not anticipate the claims because it "does not appear to be applicable to keratinocytes" (Reply, page 19, paragraph 5). These arguments have been fully considered, but they are not persuasive. The rejected claims do not limit the scope of the tissue sample. Claim 22, for example, is not included in this rejection. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 6, 14-26, 29-31, and 33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Hirobe (1992, *Journal of Cellular Physiology* 152: 337-345; reference C3 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Hirobe teaches a composition comprising cells dissociated from mouse skin tissue (page 337, column 2, paragraph 3), said composition lacking aggregates removed by a 200μm filter ("single cell suspensions," *ibid.*); and a physiological saline, specifically melanoblast defined medium, which comprises salts (page 338, column 1, paragraph 2).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in the cited claims produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Hirobe. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicants allege that the presence of bovine serum albumin (BSA) in the composition of Hirobe overcomes the rejection (Reply, page 10, last paragraph).

Applicants make allegations about "the method of cell culture" (Reply, page 11, first paragraph). These arguments have been fully considered, but they are not persuasive.

As discussed previously, serum is the liquid portion of blood; BSA is a single protein. Applicants seem to be alleging that the claim term "serum" should be interpreted "serum or any component thereof," which is improper. No such definition was provided in the specification. BSA is not serum *per se*, and serum is not BSA.

Applicant's comment "In addition, the method of cell culture requires culturing of the cells for up to 12 days, replacing the medium 4 times per week" is confusing because it is not clear whether this comment relates to the Hirobe reference or attempts to refer to the instant claims. In any case, the claims are drawn to a **composition**, not to a method of making a composition, and applicant has provided no evidence that the manner of culturing affects the properties of the composition in any patentable way.

Claims 6, 14-26, and 29-33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Noel-Hudson et al. (1993, *In Vitro Cell and Developmental Biology – Animal* 31: 508-515; reference C6 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Noel-Hudson et al. teach a composition comprising cells dissociated from human foreskin tissue (page 509, column 1, paragraph 7), said composition lacking all aggregates removed by a 200μm filter ("individual cells;" *ibid.*); and a physiological saline, specifically Hanks' solution with calcium salts (*ibid.*). Noel-Hudson et al. also teach a composition comprising skin tissue (which is inherently autologous to the donor who provided it) in an enzyme solution heated to 37°C (*(ibid.)*. The Hanks' solution of Noel-Hudson et al. comprises a calcium-free PBS to which calcium has been added; the "comprising" language in element (a) of claim 32 does not preclude the presence of calcium in the suspension.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in the cited claims produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Noel-Hudson et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that Noel-Hudson's composition is not designed for the "use of cells in a suspension for treatment of a wound" (Reply, page 11, paragraph 3). Applicant makes allegations about the method used to make the instant composition *(ibid.)*. These arguments have been fully considered, but they are not persuasive.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for

example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "for use in a method to provide cells to a patient undergoing skin grafting" (claims 32 and 33) does not affect the patentability of the claimed composition/method. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application. It is noted for the record that claim 29 and its dependents recite no intended use, so this argument is irrelevant to these claims.

Regarding the discussion of the differences between Noel-Hudson's method and that instantly disclosed, the claims are drawn to a **composition**, not to a method of making a composition, and applicant has provided no evidence that the manner of culturing affects the properties of the composition in any patentable way.

Claims 6, 14-26, 29-31, and 33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Lucas et al. (1994, U.S. Patent 5,328,695). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Lucas et al. teach a composition comprising cells dissociated from muscle and skin tissue (Example 5; column 11, lines 11-25), said composition lacking aggregates removed by a 20μm filter (column 11, lines 25-28); and a physiological saline, specifically Tyrode's TM buffer (column 11, lines 10 and 29-30). The 20μm filter of Lucas et al. is a size of "about 50μm" or "about 75μm," since the scope of "about" is not limited by the specification; furthermore, a smaller filter would remove the same aggregates as a larger one, so the composition if Lucas et al. is identical to that in claims 25 and 26.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in the cited claims produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Lucas et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that Lucas's composition is not designed for the "use of ... cells as a direct therapy" (Reply, page 11, paragraph 4). These arguments have been fully considered, but they are not persuasive.

In response to applicant's argument that Lucas does not teach using their cell suspension in "direct therapy," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art

structure is capable of performing the intended use, then it meets the claim. In this case, the explicitly stated utility of the composition of Lucas is "functional muscle tissue restoration *in vivo*" (Abstract), so the composition is clearly suitable for application to a graft.

In any case, as discussed above pertaining to the rejection over Noel-Hudson et al., compositions are defined by their physical, structural, and chemical properties, not by an intended use or application. It is noted for the record that claim 29 and its dependents recite no intended use, so this argument is irrelevant to these claims.

Claims 6, 14-26, 29-31, and 33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Lavker et al. (1996, U.S. Patent 5,556,783). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Lavker et al. teach a composition comprising cells dissociated from skin tissue (Example 5; column 8, lines 43-50), said composition lacking aggregates removed by a 200μm filter (column 8, lines 52-54); and a physiological saline, specifically phosphate buffered saline (column 8, line 51). The 200μm filter of Lavker et al. is a size of "about 150μm," since the scope of "about" is not limited by the specification.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Lavker et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicants make general arguments as to the novelty of a method of making a cell suspension (Reply, page 11, paragraph 5). These arguments have been fully considered, but they are not persuasive. As discussed above in the rejection over Noel-Hudson et al., the claims are drawn to a **composition**, not to a method of making a composition, and applicant has provided no evidence that the manner of culturing affects the properties of the composition in any patentable way.

Claims 6, 14-26, and 29-31 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Katz et al. (1998, U.S. Patent 5,786,207; on 9/28/05 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells.

Katz et al. teach a composition comprising cells dissociated from tissue (Abstract; column 14, lines 63-64).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Katz et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that Katz et al. does not teach "a cell suspension therapy as taught in the pending claims" (Reply, page 12, paragraph 1). These arguments have been fully considered, but they are not persuasive. As has been discussed above regarding other rejections, there is no method under consideration in this case. The elected claims are drawn to compositions comprising suspended cells. Arguments regarding the intended use of these compositions or methods of using these compositions are, and will continue to be, unpersuasive.

Claims 6, 14-26, 29-31, and 33 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Osborne et al. (1999, *Biomaterials* 20: 283-290; reference C4 on 6/1/04 IDS). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological

saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Osborne et al. teach a composition comprising cells dissociated from human foreskin tissue (page 284, column 2, section 2.3), said composition lacking all aggregates removed by a 200μm filter ("single cell suspension;" *ibid.*); and a physiological saline, specifically serum-free keratinocyte medium (which comprises salts) (*ibid.*).

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell suspension of Osborne et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that the method of making the composition of Osborne et al. is different from the method in which the instant composition is made (Reply, page 12, paragraph 2). These arguments have been fully considered, but they are not persuasive. As discussed above in the rejection over Noel-Hudson et al., the claims are drawn to a **composition**, not to a method of making a composition, and applicant has provided no evidence that the manner of culturing affects the properties of the composition in any patentable way.

Claims 6, 14-21, 23-26, and 29-31 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dennis et al. (2001, U.S. Patent 6,207,451). The claims are interpreted as being drawn to a composition comprising cells, said cells having been dissociated from some tissue, and a nutrient solution, said composition lacking large aggregates of cells. In some dependent claims, the tissue is skin. In some dependent claims, the nutrient media is a saline, possibly physiological saline. In some dependent claims, the composition lacks aggregates that would be removed by a filter of a particular size.

Dennis et al. teach a composition comprising cells dissociated from muscle tissue from which skin has been removed (column 12, lines 13-17), said composition lacking aggregates removed by 15 minutes of centrifugation at 1200xg (column 12, lines 20-21); and physiological salines, specifically calcium-free phosphate-buffered saline (column 6, lines 15-16); D&C solution, which comprises salts (column 5, lines 19-22, and column 6, lines 17-25); and F12 nutrient medium, which comprises salts (column 5, lines 14-17, and column 6, lines 24-26). The centrifugation step of Dennis et al. removes cell aggregates, as would the instantly claimed filters.

Once a product appearing to be substantially identical is found and an art rejection made, the burden shifts to the applicant to show an unobvious difference. In this case, this rejection might be overcome by a substantive evidentiary showing that the method steps recited in claims 5, 6, 14-21, and 25-28 produce a composition that is materially and patentably distinct from the skin cell suspension and muscle cell

suspension of Dennis et al. The discussion of product-by-process and means-plus-function limitations in the rejection over Yannas et al., above, also applies to this rejection.

Applicant alleges that Dennis does not teach using "cell suspension as a direct therapy" (Reply, page 12, paragraph 3). These arguments have been fully considered, but they are not persuasive. As has been discussed above regarding other rejections, there is no method under consideration in this case. The elected claims are drawn to compositions comprising suspended cells. Arguments regarding the intended use of these compositions or methods of using these compositions are, and will continue to be, unpersuasive.

No claims are allowed. No claims are free of the art.

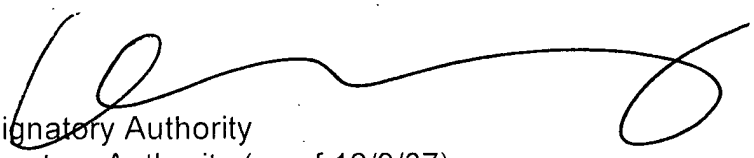
Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). In doing so, applicant is requested to refer to pages and line numbers in the as-filed specification, **not** the published application. Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Lora E Barnhart
Examiner/Partial Signatory Authority
Temporary Full Signatory Authority (as of 12/9/07)